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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,799	12/20/2001	Beuford Arlic Bogue	24720	4794

7590 01/10/2006  
Capricorn Pharma, Inc.  
6900 English Muffin Way  
Frederick, MD 21703

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,799	<b>Applicant(s)</b> BOGUE, BEUFORD ARLIE	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10-21-05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20 and 22-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of request for continued examination dated 10-21-05 is acknowledged.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of 10-21-05 has been entered.

Claims 18-20 and 22-38 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 103***

Claims 18-20 and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/40943 (WO).

WO teaches solubilizing delivery systems for poorly soluble drugs and the process of solubilizing the drugs so as to enhance the solubility of the drugs. The process of WO comprises processing of particles of at least one active agent and at least one solubilizing agent (surfactant) at temperatures below the melting points of both drug and surfactant (eutectic temperature). The processing further involves applying shear forces after melting the drug and surfactant at the eutectic temperatures (page 2, lines 20-31; page 3, lines 6-16 and lines 26-30 & page 4, lines 1-3), resulting in crystalline drug particles coated with the surfactant. Thus, the process of WO reads on the instant claimed method steps. With respect to the melting points, instant claims

require melting a mixture of drug and surfactant at a temperature above the melting point of the mixture, such that a clear mixture is formed. A review of the specification on pages 20 (lines 1-5) and 22-23 reveals that while a clear mixture results in micro and nano-crystals claimed, it is also stated that sometimes the inventive method also results in the formation of solid. Thus, it is not necessary that the claimed method always render a clear mixture. Further, instant figure 1 shows that the eutectic point of the drug and surfactant shows a melting point below the individual melting points of drug and surfactant. In this regard, WO also teaches processing drug and surfactant below their individual melting points. Even though instant claims recite "above the mixture's melting point", the said melting point of the mixture is still below their individual melting points of the drug and surfactant and thus meets the instant requirement. Accordingly, absent any unexpected results with the claimed "melting the mixture above the mixture's melting point", it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the melting temperatures suggested by WO and still prepare micro or nano-crystalline particulate drug substances.

WO teaches the claimed drugs and surfactants suitable for the invention on page 5 and 6; and their amounts on page 4, lines 17-25, all of which are claimed in the instant application. WO teaches employing micronized drug (example I) for the processing and hence meet claim 21. With respect to the particle size, WO states that the particle size before processing is less than 10 microns or even preferably less than 6 microns (page 5, lines 16-18) and absent showing evidence to the contrary, the process of applying high shear (of WO), yields crystalline particles of much smaller size. The claimed matrix,

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miscibility and the absence of bonding between the drug and the surfactant is inherent to the composition of WO because the drug and surfactant are processed in exactly the same way as described in the instant specification. WO fails to specifically teach the carrier, diluent, binder etc., for the drug. However, WO suggests mixing the surfactant coated drug particles (after processing) with various pharmaceutical ingredients such as binders, flow control agents, fillers, sweeteners etc. Accordingly, it would have been within the scope of a skilled artisan at the time of the instant invention to include any suitable pharmaceutical additive such as a binder or sweetener depending on the desired pharmaceutical effect.

### ***Response to Arguments***

Applicant's arguments filed 10-21-05 have been fully considered but they are not persuasive.

In the present action, instant claims are rejected as being obvious over the teachings of WO 99/40943 (WO). With respect to the argument regarding the processing temperatures, WO also teaches processing drug and surfactant below their individual melting points. Even though instant claims recite "above the mixture's melting point", the said melting point of the mixture is still below their individual melting points of the drug and surfactant and thus meets the instant requirement. Accordingly, absent any unexpected results with the claimed "melting the mixture above the mixture's melting point", it would have been obvious for one of ordinary skill in the art at the

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time of the instant invention to use the melting temperatures suggested by WO and still prepare micro or nano-crystalline particulate drug substances.

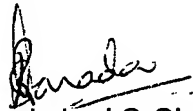
Applicants' argument that the melting point of WO is preferably below the eutectic temperature is not persuasive because the teachings of prior art are not limited to preferred embodiments and instead should be considered as a whole and the previous paragraph clearly explains how the melting temperatures of WO meet the instant claimed. As also admitted by applicants, WO clearly suggests the importance of the melting temperature and cooling step, in obtaining the desired crystals, which is also a function of active agent (teachings of WO cited by applicants in the remarks).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 9, 2006